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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,665	09/23/2003	Jean-Claude Yvin	P08425US00/BAS	1061

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,665	YVIN ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 14, 2008 has been entered.

This office action is a response to applicant's communication submitted March 14, 2008 wherein claim 1 is amended. This application was filed September 23, 2003, and makes no priority claims.

Claims 1 and 4-11 pending in this application.

Claims 1 and 4-10 as amended are examined on the merits herein.

Applicant's amendment, submitted March 14, 2008, with respect to the rejection of instant claims 1, 5, and 10 under 35 USC 102(a) for being anticipated by Miyashi et al., has been fully considered and found to be persuasive to remove the rejection as claim 1 has been amended to require a method consisting essentially of two specific structures, while the compounds used by Miyashi et al. include a plurality of different structures. Therefore the rejection is withdrawn.

Applicant's amendment, submitted March 14, 2008, with respect to the rejection of instant claims 1 and 4-10 under 35 USC 103(a) for being anticipated by Miyashi et al.

in view of Blackwill F. in view of Penney et al., has been fully considered and found to be persuasive to remove the rejection as claim 1 has been amended to require a method consisting essentially of two specific structures, while the compounds used by Miyashi et al. include a plurality of different structures. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 recite the limitation "further comprising administration of a chemotherapeutic agent" and "Further comprising administration of a potentiator". There is insufficient antecedent basis for this limitation in the claim, as the base claim 1 from which these claims depend requires that the method **consist essentially** of administering the claimed oligosaccharide. Administering an additional agent such as chemotherapeutic agents or potentiators would constitute a nontrivial additional step, meaning that these methods do not consist essentially of administering the oligosaccharide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This claim is drawn to a method comprising administering a potentiator. The specification does not disclose any methods involving potentiators or indicate that Applicant had possession of methods comprising administering potentiators. The most said in the specification is that a potentiator is a compound that improves the efficiency of the laminaroligosaccharides. Applicant has not shown any evidence of actual possession of any such compounds at the time of invention. Therefore the claim lacks antecedent basis in the base claim.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods comprising administering certain second active agents such as those chemotherapeutic agents known in the art, does not reasonably provide enablement for administration of all possible chemotherapeutic agents and potentiators. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method for treating various diseases including cancer by administering a laminarin oligosaccharide in combination with a second active agent. In order to be able to make and use the invention, one skilled in the art must be able to determine which active agents to use and to obtain said active agents.

The state of the prior art: The skilled artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen. No single chemotherapeutic drug is useful for the treatment of every case of cancer. Indeed, some types of cancer to not respond well to any known chemotherapeutic drugs. According to the Merck Manual of Diagnosis and Therapy (Reference included with PTO-892), Hepatocellular carcinomas and renal cell carcinomas are not generally improved by chemotherapy. Acute lymphoblastic leukemia, on the other hand, responds well to a number of drugs, including vincristine, anthracyclines, and aspariginases, while acute mylogenous leukemia, on the other hand, responds to fewer drugs and is usually treated with cytarabine in combination with daunorubicin or

idarubicin. Breast cancer, on the other hand, is best treated with surgery and/or radiation, but the prognosis can be improved by the addition of adjuvant chemotherapy.

The relative skill of those in the art: The level of skill in the art is high.

The predictability or unpredictability of the art: As mentioned above, no single treatment is effective for all cancers. Different cancers vary widely in their response to different chemotherapy regimens. According to the Oxford Textbook of Oncology, (Reference cited in PTO-892) "The important criteria for the tumor include its sensitivity to cytostatic drugs, its clinical stage and its mass, the presence of measurable lesions or biochemical markers, and, finally, growth characteristics," as well as, "*In vitro* sensitivity tests have been disappointing. They predict well for resistance but are of little use for sensitivity," (p. 451, right column, second paragraph) and, "For many types of cancer the potential benefit of chemotherapy has not been demonstrated in well-designed clinical trials."

Based on the known teachings of the prior art such as that stated above, one skilled in the art would recognize that it is highly unpredictable in regard to the treatment in the instant case, including treating numerous and various tumors: gynecological tumors, ovarian carcinomas, testicle tumors, prostate carcinomas, skin cancer, kidney cancer, bladder tumors, esophagus carcinomas, stomach cancer, rectal carcinomas, pancreas carcinomas, thyroid cancer, adrenal tumors, various types of leukemia and lymphomas, Hodgkin's disease, tumor illnesses of the CAN, soft-tissue sarcomas, bone sarcomas, benign and malignant mesotheliomas, especially intestine cancer, liver cancer, breast cancer, bronchial and lung carcinomas, melanomas, acute and chronic

leukemias and benign papillomatosis tumors, by performing the necessary experimentation to develop an optimized chemotherapeutic protocol for treating said cancers.

Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Additionally, the claims are interpreted to apply to new drugs for which comprehensive pharmacological data, such as optimal dosages and effectiveness against specific cancers, is not yet available.

The Breadth of the claims: he claims include methods for treatment of any cancer with any chemotherapeutic agent useful for the treatment of said cancer. The only limits are that the therapy must be administered concurrently with a 4 or 5 saccharide laminarin oligosaccharide. The specification broadly defines "potentiator" as any compound whatsoever that increases the efficiency of the oligosaccharide. Also, the term "chemotherapeutic agent" is not limited to compounds currently identified as such in the literature but includes any possible drug that can function as a chemotherapeutic agent.

The amount of direction or guidance presented: While the specification and included references give an enabling description for methods of using laminarin oligosaccharides for treating certain cancers, it does not give any guidance for the use of chemotherapeutic agents or potentiators beyond what is already known in the prior art.

The presence or absence of working examples: The specification discloses *in vivo* results showing that laminarin oligosaccharides increase TNF-alpha levels in the blood of treated mice. These examples give no support for methods of combining the claimed invention with chemotherapeutic agents or potentiators, nor do they expand the scope of chemotherapeutic agents or potentiators available to one skilled in the art. No working examples were given for the treatment of other cancers using other drugs.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable art such as chemotherapy. See MPEP 2164.

The quantity of experimentation necessary: In order to use the disclosed information to practice the claimed invention for a wide range of cancers using a wide range of drugs, a skilled practitioner of the art would develop a specific therapeutic regimen involving a specific drug or combination of drugs for each chemotherapy-responsive cancer. This would involve a process of optimizing and testing various regimens *in vivo* for each type of cancer being treated. Furthermore, as the scope of the invention includes compounds not yet known to be chemotherapeutic agents or potentiators, one skilled in the art would have to obtain and test a wide variety of different compounds for activity as chemotherapeutic agents and potentiators, a process which would involve synthesizing or isolating many different potential compounds in order to test them. Organic syntheses often involves a process of unpredictable experimentation when the compound being synthesized is novel and/or difficult, and synthesizing every last compound that would need to be tested for chemotherapeutic activity would certainly be complicated and unpredictable. The

process of isolating all the needed compounds as natural products would be even more unpredictable. Practicing the invention would therefore involve unpredictable experimentation which would constitute an undue experimental burden on the practitioner.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, especially the unpredictability of the art and the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for all possible chemotherapeutic agents and potentiators.

Claims 1 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for the treatment of specific cancers including breast, lung, oesophageal, stomach, intestinal, or colon cancer, does not reasonably provide enablement for methods and for the treatment of any cancer whatsoever, or any viral, bacterial, or fungal disease or disease of the immune system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a method of treating cancer comprising administering an immunostimulatory oligosaccharide. In order to be enabled for the claimed method, one skilled in the art must be able to develop an acceptable therapeutic protocol for every form of cancer or other disease included within the scope of the claims.

The state of the prior art: The prior art discloses various methods for treating cancer, including administering immunological agents such as oligosaccharides. Usually, different drugs are recommended against different cancers. The current state of cancer therapy is not such that a routine, predictable, and effective drug protocol exists for each and every cancer which could possibly be encountered.

With regards to generalizing specific results to the treatment of all cancers, the skilled artisan would view cancer as a group of maladies not treatable with one medicament or therapeutic regimen. No single therapy is useful for the treatment of every case of cancer. Indeed, some types of cancer to not respond well to any known

chemotherapeutic drugs. According to the Merck Manual of Diagnosis and Therapy (Reference included with PTO-892), Hepatocellular carcinomas and renal cell carcinomas are not generally improved by chemotherapy. Acute lymphoblastic leukemia, on the other hand, responds well to a number of drugs, including vincristine, anthracyclines, and aspariginases, while acute mylogenous leukemia, on the other hand, responds to fewer drugs and is usually treated with cytarabine in combination with daunorubicin or idarubicin. Breast cancer, on the other hand, is best treated with surgery and/or radiation, but the prognosis can be improved by the addition of adjuvant chemotherapy. While results for immunological therapies are less completely studied, there is no reason for one skilled in the art to expect that tumors will display less heterogeneity with respect to this therapy.

As regards bacterial, fungal, and viral diseases, these conditions encompass a vast number of different disorders caused by various widely divergent and unrelated pathogenic organisms. While certain broad-spectrum antibacterial and antifungal agents are known, specific compounds are often limited in their utility to certain classes of pathogenic organisms. (e.g. influenza virus, gram-positive bacteria)

Regarding immune disorders, many unrelated disorders involve the immune system, for example immunodeficiency diseases such as HIV or severe combined immunodeficiency, autoimmune diseases such as graft-versus host disease or rheumatoid arthritis, and other diseases such as leukemia that affect immune cells. These diseases have different causes, symptoms, and modes of action and respond to different treatments. No therapy is known that will cure all immune diseases.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: As mentioned above, no single treatment is effective for all cancers. Different cancers vary widely in their response to different chemotherapy regimens. According to the Oxford Textbook of Oncology, (Reference cited in PTO-892) "The important criteria for the tumor include its sensitivity to cytostatic drugs, its clinical stage and its mass, the presence of measurable lesions or biochemical markers, and, finally, growth characteristics," as well as, "*In vitro* sensitivity tests have been disappointing. They predict well for resistance but are of little use for sensitivity," (p. 451, right column, second paragraph) and, "For many types of cancer the potential benefit of chemotherapy has not been demonstrated in well-designed clinical trials."

Based on the known teachings of the prior art such as that stated above, one skilled in the art would recognize that it is highly unpredictable in regard to the treatment in the instant case, including treating numerous and various tumors: gynecological tumors, ovarian carcinomas, testicular tumors, prostate carcinomas, skin cancer, kidney cancer, bladder tumors, esophagus carcinomas, stomach cancer, rectal carcinomas, pancreas carcinomas, thyroid cancer, adrenal tumors, various types of leukemia and lymphomas, Hodgkin's disease, tumor illnesses of the CAN, soft-tissue sarcomas, bone sarcomas, benign and malignant mesotheliomas, especially intestine cancer, liver cancer, breast cancer, bronchial and lung carcinomas, melanomas, acute and chronic leukemias and benign papillomatosis tumors, by performing the necessary experimentation to develop an optimized dose-dense protocol for treating said cancers.

There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. The treatment of cancer is highly unpredictable due to the differing forms of cancerous cells, their location, their potential for metastases, the fact that cancer therapeutics are palliative rather than curative and that cancer treatment readily harms normal tissues. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers or tumor cells generally by enhancing the effectiveness of the immune system.

Similarly, no single treatment is expected to be useful for treating all possible pathological infections by viruses, bacteria, or fungi, owing to the diversity of different species of said pathological agents. Individual treatments must target specific features of the target organism that are not necessarily share by all species of pathological agents. Furthermore, the emergence of resistance among pathogenic organisms complicates the use of broad-spectrum therapeutic agents as any broad-spectrum

antiviral, antibiotic, or antifungal compound will provoke the emergence of resistant strains.

As regards immune diseases, the number of different diseases affecting the immune system and their lack of any single common mechanism or other feature that could be targeted by therapy makes it very difficult if not impossible to find therapeutic agents for the broad-spectrum treatment of immune disorders. There is no way to predict whether a treatment for rheumatoid arthritis, for example, will have any effect on a patient suffering from HIV.

Note that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Applicant's methods do not involve known drugs for which comprehensive pharmacological data, such as optimal dosages and effectiveness against specific cancers, is not yet available.

The Breadth of the claims: The claimed methods and compositions include methods and compositions capable of treating any cancer whatsoever, regardless of cause, parent cell type, antigen expression, and therapeutic resistance.

The amount of direction or guidance presented: Applicant's specification discloses that certain oligosaccharides can induce TNF-alpha. However, Applicant's specification does not define the limits of this therapy or provide a reasonable basis by which one skilled in the art may conclude that it is generally applicable to all cancers, viral, bacterial, or fungal infections, and immune diseases.

The presence or absence of working examples: No working examples are provided for the actual treatment of cancer or any other disease in a living organism.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as immunological cancer therapy. See MPEP 2164.

The quantity of experimentation necessary: In order to use the disclosed information to practice the claimed invention for a wide range of diseases using the claimed glucan, a skilled practitioner of the art would have to validate the therapy against a wide variety of targets, or example many different tumors, viruses, bacteria, and fungi. This would involve a process of optimizing and testing various regimens *in vivo* for each disease being treated. Because the art is still undeveloped, this process would involve unpredictable experimentation which would constitute an undue experimental burden on the practitioner.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the unpredictability of the art and the lack of guidance and working examples, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of all of the recited diseases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Ning et al. (Foreign patent CN1306003, reference included with PTO-892)

Ning et al. discloses oligosaccharides with immunostimulating and antitumor activity. (p. 1, first paragraph) The oligosaccharides include β-(1,3) glucans with 4 or 5 saccharide units and no side chains. (p. 2 third paragraph, see structure 1) The oligosaccharides can be used in a method for treating cancer by injection or oral administration. (p. 3 lines 4-5) They work by inducing expression of LI-2 and TNF-alpha in the peripheral blood. (p. 3 lines 7-10)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ning et al. (Foreign patent CN1306003, reference included with PTO-892)

The disclosure of Ning et al. is discussed above. Ning et al. does not disclose a method wherein the oligosaccharide is administered as one of the dosage forms described in claim 10.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the compounds of Ning et al. as any of the specific dosage forms described in instant claim 10. One of ordinary skill in the art would have been familiar with many different conventional dosage forms such as those recited and would have easily and routinely been able to formulate a known therapeutic agent in any appropriate dosage form.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ning et al. (Foreign patent CN1306003, reference included with PTO-892) in view of Gunasekera et al. (US patent 6476065, cited in PTO-892)

The disclosure of Ning et al. is discussed above. Ning et al. does not disclose a method of treating the specific cancers recited in claim 4, or a method comprising administering a potentiator.

Gunasekera et al. discloses immunomodulatory compounds that are useful for treating cancer. (column 2 lines 40-47) These compounds can be used for treating various cancers including breast, colon, CNS, ovarian, renal, prostate, bone, gastrointestinal, stomach, testicular, lung, leukemia, and melanoma tumors. (column 3 lines 1-4)

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the immunomodulatory compounds of Ning et al. to a patient having including breast, colon, CNS, ovarian, renal, prostate, bone, gastrointestinal, stomach, testicular, or lung cancer, or leukemia or melanoma. One of ordinary skill in the art would have been motivated to administer the oligosaccharide to these specific patients because Ning et al. discloses the compound to be an immunomodulator and Gunasekera et al. discloses that a different immunomodulator can be used for treating these specific tumors. One of ordinary skill in the art would reasonably have expected success because Ning et al. already discloses a method of using these compounds to treat cancer generally.

It would also have been obvious to one of ordinary skill in the art at the time of the invention to co-administer the compounds of Ning et al. with those of Gunasekera et al. to a patient suffering from cancer. One of ordinary skill in the art would have recognized that two known prior art therapeutic agents known to be useful for treating the same condition can be combined and co-administered using only routine, predictable experimentation. Note that the immunopotentiating compounds of Gunasekera et al. are reasonably considered to be potentiators according to the definition given on p. 4 lines 18-20 of the specification.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ning et al. (Foreign patent CN1306003, reference included with PTO-892) in view of the Merck

Manual of Diagnosis and Therapy, Seventeenth Edition. (Reference included with PTO-892, herein referred to as Merck)

The disclosure of Ning et al. is discussed above. Ning et al. does not disclose a method further comprising administering a chemotherapeutic agent.

Merck discloses that various chemotherapy drugs are used to treat different types of cancers. (p. 988, right column, paragraphs 2-3)

It would have been obvious to one of ordinary skill in the art at the time of the invention to co-administer the oligosaccharides of Ning et al. in combination with a chemotherapeutic agent. One of ordinary skill in the art would have been motivated to combine these two agents because they are both disclosed to be useful for treating the same condition, namely cancer. One of ordinary skill in the art would have reasonably expected success because both therapies are known in the prior art to be useful individually.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
8/21/2008

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623